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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/520,085 | 04/18/2005 | Thierry Massfelder | BJS-3665-133 | 9193 |

23117 7590 03/06/2008
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| EXAMINER |
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GUSSOW, ANNE

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| ART UNIT | PAPER NUMBER |
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1643

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| MAIL DATE | DELIVERY MODE |
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03/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/520,085 | Applicant(s) MASSFELDER ET AL. | |
| | Examiner ANNE M. GUSSOW | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20,23-26,31,33-35 and 38-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20,23-26,31,33-35,38-50 and 52 is/are rejected.
- 7) ☒ Claim(s) 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 10, 2008 has been entered.
2. Claim 17 has been amended.
Claims 38-52 have been added.
3. Claims 17-20, 23-26, 31, 33-35, and 38-52 are under examination.
4. The following Office Action contains NEW GROUNDS of Rejection.
5. Applicant's request for an interview with the examiner filed on January 10, 2008 is acknowledged. The request for the interview was filed on the day after an interview was held with the examiner, the examiner's supervisor, and applicant's representative. Due to the timing of the request it is unclear what new issues would be discussed in the interview. Should applicant require a further interview, applicant is requested to contact the examiner to schedule an interview.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on January 10, 2008 has been fully considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Rejections Withdrawn

7. The rejection of claims 17-20, 23-26, 31, and 33-35 under 35 U.S.C. 103(a) as being unpatentable over Ogata, et al. in view of Iwamura, et al. and Burton, et al. is withdrawn in view of applicant's amendment to the claims.

NEW GROUNDS of Rejection

Claim Objections

8. Claim 51 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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10. Claims 17-20, 23-26, 31, 33-35, and 38-50, and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a kidney cancer by administering an anti-34-53 PTHrP antibody, does not reasonably provide enablement for treating a kidney cancer with just any PTHrP intermediate region antibody or just any PTHrP C-terminal region antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to treating a kidney cancer with just any PTHrP intermediate region antibody or just any PTHrP C-terminal region antibody. The specification discloses an antibody that binds to the 34 to 53 amino acids of PTHrP and the 107 to 139 amino acids of PTHrP (see page 17). The specification discloses reduction of cell growth with the 34 to 53 amino acid antibody but not with the 107 to 139 amino acid antibody (see page 27 and figure 6).

Burton, et al. (Cancer, 1999. Vol. 86, pages 1028-1034, as cited in a previous office action) teach antibodies to the amino terminal region of PTHrP inhibits the growth of a human renal cell carcinoma cell line while expression of the 109-141 amino acid region of the PTHrP protein had a inverse correlation with the recurrence rate of renal cell carcinoma (see page 1032).

Additionally, Massfelder, et al. (Cancer Research, 2004. Vol. 64, pages 180-188) teach antibodies to the N-terminal (1-36), intermediate region (38-94), C-terminal (107-139/141), and distal C-terminal regions of PTHrP (141-173). Massfelder, et al. teach the distal C-terminal region is in the human form of PTHrP. Massfelder, et al. teach that each antibody binds the specific region of the protein in addition to the full length PTHrP protein.

There is insufficient evidence or nexus that would lead the skilled artisan to predict the ability to treat kidney cancer by administering an antibody to the intermediate region or C-terminal region of the PTHrP protein. The specification does not disclose the C-terminal region of PTHrP as inhibiting cell growth. The specification does not disclose just any intermediate region of the PTHrP protein.

In view of the lack of the predictability of the art to which the invention pertains, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed

methods are effective for treating kidney cancer, commensurate in scope with the claimed invention.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Anne M. Gussow

February 26, 2008

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643